News release

Kyowa Kirin Initiated Clinical Study of Automated Injection Device of G-Lasta® in Japan

Tokyo, Japan, February 20, 2020 ---Kyowa Kirin Co., Ltd. (TSE: 4151, President and CEO: Masashi Miyamoto, "Kyowa Kirin") announces today that a phase 1 clinical study of automated injection device of G-Lasta® [KRN125, generic name: pegfilgrastim (genetical recombination)] [*1] was started in Japan, February 19, 2020.

G-Lasta is a sustained duration form of Granulocyte Colony-Stimulating Factor (G-CSF) product[*2]. It was licensed from Kirin-Amgen Inc.[*3] to Kyowa Kirin, and launched in Japan in 2014 for decreasing the incidence of febrile neutropenia[*4] in patients receiving cancer chemotherapy. It is administered at medical institutions at least one day after chemotherapy. This automated injection device has a function to deliver G-Lasta into patient's body the day after chemotherapy, and is applied to patients on the same day of chemotherapy. Therefore, it is expected to reduce the ambulant burden on patients, and contributes to reducing burden on healthcare professionals.

"Burden on patient's body is heavy after chemotherapy, and it is very important to reduce it." said Takeyoshi Yamashita, Ph.D., Executive officer, Director of Corporate Strategy & Planning Department of Kyowa Kirin. "We believe that this device contributes to reducing the burden on patients."

Kyowa Kirin will file an application for manufacturing and marketing approval with Japan's Ministry of Health, Labor and Welfare (MHLW) using this phase 1 clinical study's data which is objected to evaluate safety of G-Lasta. This device is co-developed with a domestic medical equipment manufacturer.

The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

<About the Clinical Study>

Indication	Decrease the incidence of febrile neutropenia in patients receiving cancer chemotherapy
Phase	Phase 1
Design	Multicenter open-label single-arm study
Administration group	KRN125 group
Primary evaluation items	Safety
Sample size	30
Countries	Japan

***1: About G-Lasta®**

G-Lasta is a sustained duration form of Granulocyte Colony-Stimulating Factor (G-CSF) product, which is produced by PEGylation[*5] of filgrastim, for decreasing the incidence of febrile neutropenia in patients receiving cancer chemotherapy. Pegfilgrastim, originally generated by Amgen, Inc., was licensed from Kirin-Amgen Inc., to Kyowa Kirin.

***2: About Granulocyte Colony-Stimulating Factor (G-CSF) product**

G-CSF is a protein produced by using gene recombination. G-CSF selectively stimulates production of neutrophils and also enhances the neutrophil function. Based on this mechanism, G-CSF is used to accelerate recovery from chemotherapy-induced neutropenia, and it reduces various risks associated with neutropenia.

***3: About Kirin-Amgen Inc.**

At the time of its licensing, it was a joint venture between Amgen and Kirin Holdings. In 2017, they have agreed to terminate the joint venture. And it is now a subsidiary of Amgen.

***4: About febrile neutropenia**

Myelosuppressive chemotherapy causes low neutrophil count, i.e. neutropenia, which can raise risk of infections. Neutropenia with fever, known as febrile neutropenia, can be a sign of a serious infection and the patient needs to be given appropriate treatments.

***5: About PEGylation**

PEGylation is a chemical modification of protein bound by polyethylene glycol. PEGylation enables protein to suppress degradation and to reduce clearance in human body, resulting in improving retention of the protein in the blood stream and prolonging the duration of its activities.